UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

BRAINTREE LABORATORIES, INC., Plaintiff, v. BRECKENRIDGE PHARMACEUTICAL, INC., Defendant.	Civil Action No. 12-cv-6851-AJN [rel. 14-cv-8147-AJN] ECF Case

PLAINTIFF BRAINTREE LABORATORIES INC.'S OPPOSITION TO DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

I. INTRODUCTION 1

II. STATEMENT OF FACTS 2

A. Background of this Litigation 2
B. The '149 Patent and the Invention of SUPREP 3
C. SUPREP Bowel Prep Kit 4
D. Breckenridge's Proposed Generic Copy of SUPREP 4
E. The Novel Litigation 4
1. Initial District Court Proceedings 5
2. Federal Circuit Appeal 6
3. District Court Remand Proceedings 7

III. LEGAL STANDARD 7

IV. THE FEDERAL CIRCUIT HAS REJECTED THE SOLE ARGUMENT BRECKENRIDGE PRESENTS IN ITS MOTION 8

V. BRECKENRIDGE'S PROPOSED GENERIC COPY OF SUPREP WILL INFRINGE CLAIMS 15, 18, 19, 20, AND 23 OF THE '149 PATENT 10

A. Breckenridge's Proposed Generic Copy of SUPREP Infringes the "about 100 ml to about 500 ml" limitation of the Claims of the '149 Patent 10

VI. BRECKENRIDGE'S NON-INFRINGEMENT POSITION IS FLAWED AND INVITES ERROR 12

A. Breckenridge's Motion Improperly Reargues Claim Construction 12
B. Breckenridge's Non-infringement Argument Relies on a Mischaracterization of its Proposed Generic Copy of SUPREP and its Proposed Indication 17
C. Breckenridge Misapprehends Infringement Under § 271(e) 18
D. Braintree's Infringement Argument Does Not Improperly Divide the Accused Product 19
E. Breckenridge's Assertion that Purgation is an "Off-Label" Use Lacks Merit 21
1. The Cases Breckenridge Cites Are Inapposite 22

VII. CONCLUSION 25

TABLE OF AUTHORITIES

Page(s)

CASES

Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.,
467 F.3d 1370 (Fed. Cir. 2006).....13

Accent Packaging, Inc. v. Leggett & Platt, Inc.,
707 F.3d 1318 (Fed. Cir. 2013).....14, 21

Acumed LLC v. Stryker Corp.,
483 F.3d 800 (Fed. Cir. 2007).....8

Allergan, Inc. v. Alcon Laboratories, Inc.,
324 F.3d 1322 (Fed. Cir. 2003).....22, 23

AstraZeneca LP v. Apotex, Inc.,
633 F.3d 1042 (Fed. Cir. 2010).....8, 12, 22

AstraZeneca Pharmaceuticals LP v. Apotex Corp.,
669 F.3d 1370 (Fed. Cir. 2012).....23

Bayer AG v. Elan Pharmaceutical Research Corp.,
212 F.3d 1241 (Fed. Cir. 2000).....23, 24, 25

Bayer Schering Pharma AG v. Lupin, Ltd.,
676 F.3d 1316 (Fed. Cir. 2012).....22, 23, 24, 25

Douglas Dynamics, LLC v. Buyers Products Co.,
717 F.3d 1336 (Fed. Cir. 2013).....14

Dow Chemical Co. v. NOVA Chemicals Corp. (Canada),
629 F. Supp. 2d 397 (D. Del. 2009).....19, 20

Ecolab, Inc. v. Envirochem, Inc.,
264 F.3d 1358 (Fed. Cir. 2001).....19, 20

Eli Lilly & Co. v. Medtronic, Inc.,
496 U.S. 661 (1990).....19

Estee Lauder Inc. v. L'Oreal, S.A.,
129 F.3d 588 (Fed. Cir. 1997).....16

Falana v. Kent State University,
669 F.3d 1349 (Fed. Cir. 2012).....15

Ferring B.V. v. Watson Laboratories, Inc., Florida,
764 F.3d 1401 (Fed. Cir. 2014).....18

Glaxo, Inc. v. Novopharm, Ltd.,
110 F.3d 1562 (Fed. Cir. 1997).....8, 11, 18

Global-Tech Appliances, Inc. v. SEB S.A.,
131 S. Ct. 2060 (2011).....8

Halliburton Energy Services, Inc. v. M-I LLC,
514 F. 3d 1244 (Fed. Cir. 2008).....14

In re Swinehart,
439 F. 2d 210 (C.C.P.A. 1971) 14

Jeneric/Pentron, Inc. v. Dillon Co., Inc.,
205 F.3d 1377 (Fed. Cir. 2000).....19, 21

Litecubes, LLC v. Northern Light Products, Inc.,
523 F.3d 1353 (Fed. Cir. 2008).....9

Mangosoft, Inc. v. Oracle Corp.,
525 F.3d 1327 (Fed. Cir. 2008)..... 14-15

Matsushita Electric Industrial Co., Ltd. v. Zenith Radio Corp.,
475 U.S. 574 (1986).....7

Novartis Pharmaceuticals Corp. v. Apotex Corp.,
No. 02CIV.8917 (KMW)(HBP), 2006 WL 626058 (S.D.N.Y. Mar. 13, 2006).....19

Perkin-Elmer Corp. v. Westinghouse Electric Corp.,
822 F.2d 1528 (Fed.Cir.1987).....21

Phillips v. AWH Corp.,
415 F.3d 1303 (Fed. Cir. 2005) (en banc).....15

Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.,
655 F.3d 1364 (Fed. Cir. 2011).....8

Sundance, Inc. v. DeMonte Fabricating Ltd.,
550 F.3d 1356 (Fed. Cir. 2008).....16

Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.,
785 F.3d 625 (Fed. Cir. 2015).....24

Unique Concepts, Inc. v. Brown,
939 F.2d 1558 (Fed. Cir. 1991).....11, 14, 21

Warner-Lambert Co. v. Apotex Corp.,
316 F.3d 1348 (Fed. Cir. 2003)..... *passim*

STATUTES, REGULATIONS AND RULES

Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. § 355 18

21 U.S.C. § 355(b)(i) 2

35 U.S.C. § 271 8

35 U.S.C. § 271(a) 8, 19

35 U.S.C. § 271(b) 8

35 U.S.C. § 271(e) 3, 18, 19

35 U.S.C. § 271(e)(2) 7, 19, 23

21 C.F.R. Part 5 18

Fed. R. Civ. P. 56(a) 7

OTHER AUTHORITIES

Chisum, Donald A., 3-8 *Chisum on Patents* § 8.04 (2013) 14

Braintree Laboratories, Inc. v. Novel Laboratories, Inc., No. 2013-1438, Oral Arguments (Fed. Cir. Feb. 4, 2014), *available at* http://oralarguments.cafc.uscourts.gov/Audiomp3/2013-1438.mp3 6-7

I. INTRODUCTION

The sole argument of Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge")[1] in its summary judgment motion is that one bottle of its proposed copy of Braintree's SUPREP® Bowel Prep Kit ("SUPREP") cannot, as a matter of law, infringe U.S. Patent No. 6,946,149 ("the '149 patent"). Breckenridge's motion fails because that argument has been considered and expressly rejected both by the District of New Jersey and the Federal Circuit in *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, D.N.J., C.A. No. 11-1341 ("the *Novel Case*"). The Federal Circuit explicitly held that one bottle of generic SUPREP—with a volume of "from about 100 ml to about 500 ml"—can infringe the '149 patent. The Court held that "Braintree's 'one bottle' infringement theory… can prevail" under the construction of "purgation" that it affirmed on appeal. Ex. 13, at 6-8, 10[2] ("We affirm the district court's construction of 'purgation,' and we likewise affirm the district court's finding that one (half-dose) bottle of SUPREP practices this claim limitation"). The Federal Circuit decision in the *Novel Case*, and its adopted claim construction, are binding on Breckenridge and on this Court. Breckenridge's motion for summary judgment should be denied on this basis alone.

Breckenridge's motion is substantively meritless as well. It is ***undisputed*** that each diluted bottle of Breckenridge's proposed copy of SUPREP will satisfy each and every element of the asserted claims. SF 7, 24-27, 41, 46[3]; Dkt. 41, ¶ 3. Breckenridge attempts to avoid this

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[1] The defendant in this case was originally Cypress Pharmaceutical, Inc. ("Cypress"). On October 15, 2013, Cypress filed a Motion to Substitute a Party, requesting that the Court substitute Breckenridge for Cypress in this matter. Dkt. 61. This Court granted that Motion on October 16, 2013. Dkt. 62. For the avoidance of confusion, Braintree uses the term "Breckenridge" throughout this brief, for events both before and after October 2013.

[2] References in this document to "Ex." refer to exhibits to the Declaration of Jennifer Brown in Support of Braintree's Opposition to Breckenridge's Motion for Summary Judgment of Non-infringement ("Brown Declaration"), filed concurrently herewith.

[3] All references to "SF" are to the Stipulated Facts for Purposes of Breckenridge's Motion for Summary Judgment of Non-infringement, which is attached as Exhibit 11 to the Brown Declaration, filed concurrently herewith.

inescapable fact by arguing that infringement must be determined by comparing the combined *two* bottles of its product to the asserted claims. This is contrary to the Federal Circuit's holding in the *Novel Case*. Breckenridge cites no case law to support its position. Nor does Breckenridge explain why it urges this Court to ignore the claim requirement that the composition is "for inducing purgation," which – it is undisputed – is accomplished by one bottle of Breckenridge's proposed copy of SUPREP.

Instead, Breckenridge devotes much of its brief to discussion of the '149 patent file history and specification. But those sources are relevant only to claim construction – a step that Breckenridge has waived in this litigation – not to an infringement analysis, which requires a comparison of the claims as construed by the Federal Circuit to the product to be sold. The result of the proper infringement analysis is beyond dispute: each bottle of Breckenridge's copy of SUPREP, when diluted according to Breckenridge's proposed labeling, infringes the asserted claims of the '149 patent because each bottle is a composition of "about 100 ml to about 500 ml" "for inducing purgation." Breckenridge's motion should be denied.

II. STATEMENT OF FACTS

A. Background of this Litigation

Braintree holds New Drug Application No. 22372 for SUPREP, which is FDA-approved for "cleansing of the colon in preparation for colonoscopy in adults." *See* SF 1, 4; BMF 14, 17.[4] The FDA approved SUPREP on August 5, 2010 after substantial research and development, and extensive clinical trials by Braintree. *See* SF 2, 45. Pursuant to 21 U.S.C. § 355(b)(i), SUPREP is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* as being covered by one or more claims of Braintree's '149 patent. BMF 16-20.

[4] All references to "BMF" are to Braintree's Statement of Material Facts in Support of Its Opposition to Breckenridge's Motion for Summary Judgment of Non-infringement, filed concurrently herewith.

On March 15, 2012, Breckenridge submitted Abbreviated New Drug Application ("ANDA") No. 204135 seeking approval to market a generic copy of SUPREP before expiration of the '149 patent. *See* SF 9, 10; BMF 20, 40, 42, 44. After receiving a Paragraph IV letter from Breckenridge on or around July 31, 2012, Braintree filed this case against Breckenridge on September 11, 2012, for enforcement of the '149 patent pursuant to 35 U.S.C. § 271(e). BMF 1, 14, 18, 20, 41, 44, 55. Braintree asserts that Breckenridge and its proposed generic product infringe composition claims 15 and 18, and method claims 19, 20 and 23 of the '149 patent.

Breckenridge has waived all defenses in this case other than the non-infringement defense it presents in its summary judgment motion, based on the "from about 100 ml to about 500 ml" limitation in the asserted claims. Ex. 1, at 10:7-13; Dkt. 41, ¶¶ 3, 6. Breckenridge has also waived any opportunity for claim construction by this Court. If the Court denies Breckenridge's motion, "[Breckenridge] stipulates that its proposed generic version of Braintree's SUPREP described in [Breckenridge's] ANDA No. 204135 … infringes claims 15, 18, 19, 20, and 23 of the '149 Patent." *See* Dkt. 41, ¶ 3; *see also* BMF 123; Ex. 1, at 10:7-13.

B. The '149 Patent and the Invention of SUPREP

The '149 patent was filed on August 30, 2002 and issued on September 20, 2005.[5] BMF 2-4. It expires no earlier than March 7, 2023. BMF 20. The '149 patent discloses and claims the invention by Drs. John Fordtran and Mark Cleveland of novel, low-volume compositions of sulfate salts in an aqueous hypertonic solution that induce purgation while avoiding dangerous (in some cases life-threatening) electrolyte abnormalities caused by the sodium phosphate-based prior art solutions. *See* Ex. 6; *see generally* Dkt. 86-4; *see also* Dkt. 86-15, at 2-3; BMF 6, 13.

[5] On June 30, 2009, the United States Patent & Trademark Office ("PTO") confirmed the patentability of the '149 patent after Braintree voluntarily requested that the PTO reexamine the '149 patent in view of newly identified prior art. *See* Ex. 3 at BRTSUP00000622-39; Ex. 4 at BRTSUP00000471-76; Dkt. 86-3.

C. SUPREP Bowel Prep Kit

Braintree makes and sells SUPREP as a kit containing two 6-ounce bottles of an aqueous hypertonic solution of potassium sulfate, magnesium sulfate, and sodium sulfate.[6] Ex. 10; BMF 21, 24, 28-29, 87. The FDA-approved label for SUPREP instructs patients to take the product in two administrations to achieve the goal of colon cleansing in preparation for a colonoscopy:

- First, the patient is directed to consume one 6-ounce bottle of SUPREP diluted with 10 ounces of water—for a total of 16 ounces (473 ml). *See* Ex. 10, at BRTSUP00000130. Consumption of that first diluted bottle will induce the patient to have a purgation, *i.e*., an evacuation of a copious amount of stool from the bowels after oral administration of the solution. *See id.* at BRTSUP00000136; SF 7; BMF 23-33; Dkt. No. 41, at ¶ 5; Ex. 6, at 11.
- Second, after waiting 10-12 hours, the patient is directed to consume a second 6-ounce bottle of SUPREP diluted with 10 ounces of water—again totaling 473 ml. *See* Ex. 10, at BRTSUP00000130. Consumption of this second diluted bottle will induce the patient to have another purgation. *See id.* at BRTSUP00000136; SF 6, 7, 8; BMF 31-37.
- Ingestion of both bottles, 10-12 hours apart, helps to achieve the goal of adequate cleansing of the colon for colonoscopy procedures. *See id*. at BRTSUP000000130; SF 8; BMF 26, 38.

D. Breckenridge's Proposed Generic Copy of SUPREP

Breckenridge's proposed generic product, described in Breckenridge's ANDA No. 204135, is a copy of SUPREP. SF 11, 12. It is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to SUPREP. SF 14-20; BMF 43, 45-53. The proposed label for Breckenridge's proposed generic product is, in all relevant respects, the same as the FDA-approved label for SUPREP. SF 28-30; BMF 65. Breckenridge's proposed generic product will, if approved, have the same split-dose administration and the same indication as SUPREP: cleansing of the colon in preparation for colonoscopy in adults. SF 4, 20; BMF 17, 54.

E. The Novel Litigation

Breckenridge is not the first ANDA filer seeking to market a generic copy of SUPREP.

[6] In a declaration filed concurrently herewith, Dr. David Peura explains how SUPREP works and how it is different from other colonoscopy prep products. *See* Peura Decl., ¶¶ 27-55. Citations to "Peura Decl." refer to the Declaration of David A. Peura, M.D. in Support of Braintree's Opposition to Breckenridge's Motion for Summary Judgment of Non-infringement, filed concurrently herewith.

In January 2011, after receiving a Paragraph IV letter from Novel Laboratories, Inc. ("Novel"), Braintree sued Novel for patent infringement in the U.S. District Court for the District of New Jersey. Judge Peter G. Sheridan was assigned the case. BMF 84, 86.

1. Initial District Court Proceedings

During two years of district court proceedings in the *Novel Case*, Judge Sheridan addressed, among other issues, claim construction, infringement, and validity of the '149 patent.[7] *See generally* Ex. 6; Dkt. 86-15; Ex. 5; BMF 86-96. Judge Sheridan found that Novel's proposed generic copy of SUPREP—which Breckenridge admits "is, in all relevant and material respects, identical" to Breckenridge's generic copy of SUPREP—infringes the '149 patent claims, and its proposed label induces infringement. *See* Dkt. 86-15; Dkt. No. 41, at ¶ 7; BMF 85, 90-96.[8] After a six-day trial, Judge Sheridan held that the '149 patent was valid. *See* Ex. 5.

In concluding that Novel's proposed generic copy of SUPREP infringes the asserted claims of the '149 patent, Judge Sheridan:

- Construed "purgation" to mean "an evacuation of a copious amount of stool from the bowels after oral administration of the solution," and thus rejected Novel's argument that "purgation" requires a complete cleansing of the colon. *See* Ex. 6, at 5-6; BMF 89. Based on this conclusion, Judge Sheridan rejected Novel's argument that its product did not infringe because the total volume of two bottles required for cleansing fell outside the 100 mL to 500 mL limitation in the asserted claims. *See* Dkt. 86-15, at 14-16.
- Rejected Novel's attempt to import a cleansing limitation into the claims of the '149 patent based on alleged "admissions" in the file history. *See* Dkt. 86-15, at 16-17; BMF 92.
- Rejected Novel's non-infringement argument based on *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003) and its progeny. He found that Novel's argument was

[7] Judge Sheridan construed four claim terms in the '149 patent after full briefing on claim construction, totaling nearly 120 pages, 100 pages of expert declarations, and a 2-day *Markman* hearing during which he heard a technology tutorial delivered by the '149 patent inventors, lengthy testimony from three expert witnesses, and argument. *See* Ex. 6.

[8] Judge Sheridan made his decision after considering full briefing on Braintree's Motion for Summary Judgment of Infringement, full briefing on Novel's Motion for Summary Judgment of Non-infringement, and oral argument on those two motions. *See Novel Case*, Dkt. Nos. 143, 159, 173, 176, 203, 207; Dkt. 86-15 (*Novel Case* Summary Judgment Opinion). Judge Sheridan later confirmed his finding of infringement when he denied Novel's Motion for Reconsideration. See Ex. 12 (*Novel Case* Order Denying Motion for Reconsideration).

> "without merit…[b]ecause purgation is the method by which SUPREP achieves the FDA-approved indication of colon cleansing, [and therefore] purgation cannot be an off-label use for SUPREP." *See* Dkt. 86-15, at 16; BMF 93-95.

Judge Sheridan entered final judgment in favor of Braintree. *See* Ex. 7.

2. Federal Circuit Appeal

Novel appealed to the Federal Circuit, arguing that the district court erred: (1) in its construction of the claim terms "purgation" and "clinically significant electrolyte shifts," (2) in its infringement finding, and (3) in its validity finding. BMF 98.

The Federal Circuit affirmed Judge Sheridan's construction of "purgation," rejecting Novel's argument that "purgation" and "cleansing" were synonymous. *See* Ex. 13, at 7; BMF 99, 101-105. Confirming that "Braintree's 'one bottle' infringement theory…can prevail" under the affirmed construction of "purgation," the Federal Circuit also found that "one (half-dose) bottle of SUPREP practices" the purgation claim limitation, Ex. 13 at 10, and that one diluted bottle of SUPREP, with a total volume of 473 mL, falls within the 100 ml to 500 ml limitation, *id.* at 6; BMF 105-110.

The Federal Circuit affirmed the district court's validity findings. Ex. 13, at 12-17; BMF 111. It, however, reversed the district court's construction of "clinically significant electrolyte shifts," vacated the infringement finding with respect to that claim limitation, and remanded for the limited purpose of further factual findings on that issue. *Id.* at 8-12; BMF 112-114.

Judge Dyk's dissent argued against "Braintree's 'one bottle' theory," and suggested that the Court should have found non-infringement because "Novel's ANDA does not meet the volume limitation of the asserted claims." Ex. 13, Dissent of Dyk, J., at 2-11; BMF 115. Judge Dyk cited *Warner-Lambert* and related cases in support. *Id.* at 3-7. Judge Dyk raised this argument during oral argument as well, in questions to both Novel's and Braintree's counsel. *See* Oral Argument at 1:00, 15:20, *Braintree Labs., Inc. v. Novel Labs., Inc.*, No. 2013-1438

(Fed. Cir.), available at http://oralarguments.cafc.uscourts.gov/Audiomp3/2013-1438.mp3. The majority of the panel disagreed with and did not join Judge Dyk's dissent. BMF 116. This was confirmed by Judge Dyk, when he distinguished his non-infringement argument from the "*contrary conclusion* reached by the majority." Ex. 13, Dissent of Dyk, J. at 11 (emphasis added); BMF 116.

Following the Federal Circuit panel's decision, Novel filed a Petition for Rehearing *en Banc*, in which it argued that the panel majority erred by not adopting Judge Dyk's dissenting non-infringement position. BMF 118; *see generally* Ex. 14. The Federal Circuit denied Novel's Petition for Rehearing *en Banc*. Dkt. 86-19, at 2; BMF 119.

3. District Court Remand Proceedings

On remand, Judge Sheridan held a 3-day trial, including testimony from four expert witnesses, on the issue of whether Novel's proposed generic product would produce clinically significant electrolyte shifts in the general class of persons to whom is it directed. BMF 120. On June 1, 2015, Judge Sheridan issued his findings of fact and conclusions of law, finding that Novel's proposed generic copy of SUPREP would, if marketed and sold, infringe claims 15 and 18, and induce infringement of claims 19, 20, and 23 of the '149 Patent. Ex. 15; BMF 121-122. Novel noticed an appeal to the Federal Circuit, and its opening brief is due on August 10, 2015.

III. LEGAL STANDARD

Summary judgment is appropriate only if Breckenridge shows that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Breckenridge bears the burden of proving that there is no genuine dispute as to any material fact that its proposed generic copy of SUPREP does not infringe the '149 patent. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n. 10 (1986).

The infringement analysis under 35 U.S.C. § 271(e)(2) in the ANDA context is the same

as "traditional" infringement analysis under 35 U.S.C. § 271(a). *Warner-Lambert*, 316 F.3d at 1365. The relevant inquiry is "whether the patentee has proven by a preponderance of the evidence that the alleged infringer will likely market an infringing product. What is likely to be sold, or, preferably, what will be sold, will ultimately determine whether infringement exists." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 15670 (Fed. Cir. 1997) (emphasis added).

Whether a product infringes under 35 U.S.C. § 271 is determined through a two-step analysis. "[F]irst, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007) (citation omitted). "To prove infringement, a plaintiff must prove the presence of each and every claim element or its equivalent in the accused method or device." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 655 F.3d 1364, 1378 (Fed. Cir. 2011). A person directly infringes § 271(a) if that person makes, uses, offers to sell, or sells any patented invention, within the U.S., or imports into the U.S. any patented invention, without authorization of the patent holder. A party may indirectly infringe a patent under 35 U.S.C. § 271(b) by inducing another party to make, use, offer to sell, or sell a patented invention in the United States. *See* 35 U.S.C. § 271(b). This requires specific intent to induce the infringement, which is established where an accused infringer advertises or provides instructions promoting the infringing use. *See Global-Tech Appliances, Inc. v. SEB S.A.*, 131 S. Ct. 2060, 2062 (2011); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1059-60 (Fed. Cir. 2010) ("*AstraZeneca 2010*").

IV. THE FEDERAL CIRCUIT HAS REJECTED THE SOLE ARGUMENT BRECKENRIDGE PRESENTS IN ITS MOTION

Breckenridge's sole non-infringement argument in its summary judgment motion is precluded by binding Federal Circuit law. Breckenridge argues that this Court may not, as a matter of law, find infringement based on one bottle of Breckenridge's copy of SUPREP

because "one bottle is only ***half*** of the proposed product." MSJ 3; *see also id.* at 19 ("Braintree's 'One Bottle Infringement' Theory Improperly Divides the Accused Product"). Breckenridge's position is directly contrary to and inconsistent with the unambiguous language of the Federal Circuit's opinion in the *Novel Case*, which held:

> Braintree's 'one bottle' infringement theory asserts that one (half-dose) bottle of SUPREP, diluted with water to become a sixteen ounce solution, falls within the asserted claims. ***This infringement theory can prevail if purgation means the 'evacuation of a copious amount of stool from the bowels after oral administration of the solution,' which is something less than a full cleansing.***

Ex. 13, at 6 (emphasis added). The Court then affirmed the stated construction of "purgation," and found that "one (half-dose) bottle of SUPREP practices this claim limitation." *Id.* at 10. The Federal Circuit thus confirmed – contrary to Breckenridge's insistence – that a one-bottle infringement analysis is proper.

Breckenridge argues that the Federal Circuit did not consider Breckenridge's argument because it was not raised by Novel, MSJ 4-5. But whether Novel raised it is irrelevant because the argument was raised by Judge Dyk in a *dissenting opinion* that the panel majority did not adopt.[9] Breckenridge admits that Judge Dyk's dissent presented "the volume limitation issue that is the basis of Breckenridge's current motion." MSJ 4; BMF 117; *see also* Dkt. 73, at 3. Instead of accepting Judge Dyk's non-infringement theory, the panel majority rejected it and held that the "one bottle infringement theory…can prevail." The dissent recognized that the panel majority's holding was a "contrary conclusion" to its position. *See* Ex. 13, Dissent of Dyk, J. at 11 ("Because Novel's ANDA does not meet the volume limitation of the asserted claims … it cannot infringe the '149 patent. I respectfully dissent from the ***contrary conclusion*** reached by the majority") (emphasis added). The panel majority's decision is a rejection of Judge Dyk's –

[9] The Federal Circuit has discretion to consider an argument not raised in the parties' briefs. *See, e.g., Litecubes,LLC v. N. Light Products, Inc.*, 523 F.3d 1353, 1369 (Fed. Cir. 2008).

and Breckenridge's – position. Breckenridge argues in its motion that this Court adopt Judge Dyk's dissenting theory and find non-infringement as a matter of law. But a majority of the panel rejected that theory and remanded the case for further fact-finding relating to infringement of a different claim limitation. Ex. 13, at 12. Had the panel majority accepted Judge Dyk's view, they would not have remanded the case. This Court should not premise any legal conclusion on a dissenting opinion because that would be error as a matter of law.[10]

Given the Federal Circuit's holding in the *Novel Case*, this Court need not consider Breckenridge's substantive arguments, because its position is precluded by binding precedent.

V. BRECKENRIDGE'S PROPOSED GENERIC COPY OF SUPREP WILL INFRINGE CLAIMS 15, 18, 19, 20, AND 23 OF THE '149 PATENT

Should the Court reach the substance of Breckenridge's motion, this Court should deny the motion: Breckenridge's proposed generic product infringes composition claims 15 and 18, and its proposed label induces infringement of method claims 19, 20 and 23 of the '149 patent.

A. Breckenridge's Proposed Generic Copy of SUPREP Infringes the "about 100 ml to about 500 ml" limitation of the Claims of the '149 Patent

Having agreed to present no other defenses or arguments (*see* Dkt. 41, ¶ 3), Breckenridge relies on its sole non-infringement argument that its proposed generic copy of SUPREP does not meet the "about 100 ml to about 500 ml" limitation of the asserted composition claims (reexamined claims 15 and 18) and method claims (claims 19, 20, and 23) of the '149 patent. Breckenridge is wrong as a matter of fact and law.

Re-examined claim 15 of the '149 patent claims:

> ***A composition for inducing purgation of the colon of a patient***, ***the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution*** comprising an effective amount of Na_2SO_4, an effective amount of

[10]Novel moved for *en banc* consideration of Judge Dyk's argument, and the motion was denied, with no dissent from the denial. *See* Ex. 14; Dkt. 86-19.

> $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

See Dkt. 86-3, at Claim 15 (emphasis added). This claim, as construed by Judge Sheridan and affirmed by the Federal Circuit, requires a composition of about 100 ml to about 500 ml "*for inducing purgation*" – that is, for inducing "an evacuation of a copious amount of stool from the bowels after oral administration of the solution." *See* Ex. 6, at 11. All elements of this claim language – like all limitations in the claim – must be applied when considering infringement. *See Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991) ("All the limitations of a claim must be considered meaningful"); *Glaxo,* 110 F.3d at 1566 ("It is elementary patent law that all limitations are material.").

Based on the stipulated facts and the construction of "purgation" affirmed by the Federal Circuit, there can be no dispute that Breckenridge's proposed copy of SUPREP is "[a] composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution." Specifically:

- Breckenridge's proposed generic copy of SUPREP will be sold as a kit containing two 6-ounce bottles of solution. SF 22; BMF 57.
- The proposed labeling for Breckenridge's proposed generic copy of SUPREP requires that each bottle be diluted with water to 16 ounces before administration. SF 23; BMF 58.
- When the first 6-ounce bottle of Breckenridge's proposed generic copy of SUPREP is diluted with water to 16 ounces (pursuant to its proposed labeling), the resulting aqueous hypertonic solution will have a volume of 473 ml. SF 27; BMF 62.
- When that first 6-ounce bottle of Breckenridge's proposed generic copy of SUPREP diluted with water to 16 ounces is consumed by a patient (as is required by its proposed labeling), that solution will "induce purgation" of the patient's colon. SF 24, 25; BMF 59-60, 64.
- When the second 6-ounce bottle of Breckenridge's proposed generic copy of SUPREP is diluted with water to 16 ounces (pursuant to its proposed labeling), the resulting aqueous hypertonic solution will have a volume of 473 ml. SF 27; BMF 62.
- When that second 6-ounce bottle of Breckenridge's proposed generic copy of SUPREP diluted with water to 16 ounces is consumed by a patient (10-12 hours after the patient consumes the diluted first bottle, as is required by its proposed labeling), that solution will

"induce purgation" of the patient's colon. SF 41; BMF 77.

Therefore, Breckenridge's proposed generic copy of SUPREP will contain two bottles of solution that will each, when prepared according to Breckenridge's proposed labeling, necessarily infringe claims 15 and 18 of the '149 patent because each will separately have a volume between 100 ml and 500 ml and induce purgation. *See* Ex. 13, at 7-8, 10.

Breckenridge will also induce infringement of method claims 19, 20, and 23 of the '149 patent based on the facts stipulated by the parties. Breckenridge intends for doctors to prescribe its proposed generic product for patients to use according to its label (SF 30-32), and the label explicitly instructs users to infringe the claims of the '149 patent as described above. SF 28, 30-32, 34; BMF 65-71; *see AstraZeneca 2010*, 633 F.3d at 1060 (finding intent to induce infringement based on the product label authorizing the patented use, which "would inevitably lead some consumers to practice the claimed method").[11]

VI. BRECKENRIDGE'S NON-INFRINGEMENT POSITION IS FLAWED AND INVITES ERROR

A. Breckenridge's Motion Improperly Reargues Claim Construction

Despite its assertion that "[t]his Court does not need to conduct formal claim construction for purposes of Breckenridge's current motion" (MSJ at 15), Breckenridge spends several pages of its brief analyzing the specification, the disclosed preferred embodiments, and the file history

[11] Claim 23 is directed to "[a] method for inducing colonic purgation in a patient according to claim 20, wherein the effective amount of the composition is administered in two or more doses within a treatment period." Dkt. 86-4, at claim 23. A person of ordinary skill in the art understands that the reference in claim 23 to "***the*** effective amount of ***the*** composition" has antecedent basis from independent claim 15 (through claim 20), which makes clear that the term "effective amount" is the effective amount "for inducing purgation." *See id*. at claims 20, 23 (emphasis added); Dkt. 86-3, at claim 15 (emphasis added). Judge Sheridan in the *Novel Case* construed "effective amount" to mean "the amount and combination of salts necessary *to produce a colonic purgation*, while not producing clinically significant electrolyte shifts," Ex. 6, at 11 (emphasis added). Novel did not appeal that construction, and Breckenridge cannot challenge it. Ex. 13 (Federal Circuit Decision), at 7; Dkt. 41, ¶¶ 3-6. Therefore, claim 23 covers a method in which *the effective amount of the composition to induce purgation* (which also meets the other limitations of claim 15) is administered two or more times within a treatment period. *See* Peura Decl. ¶¶ 73-77. Breckenridge's assertion that claim 23 supports its non-infringement argument, MSJ at 24-25, therefore must fail.

of the '149 patent. MSJ 7-12. Based on that analysis, Breckenridge argues that "the phrase 'about 100 ml to about 500 ml' in the reexamined claims limits the total volume ***of the claimed composition***; it does not refer to some minimum amount of solution required to induce purgation." MSJ at 16 (emphasis in original). This is plainly a claim construction-based infringement argument, attempting to read a cleansing requirement into the claim term "from about 100 ml to about 500 ml." Putting aside Breckenridge's stipulation that no claim construction is required, its argument can only succeed if (1) "for inducing purgation" is improperly read out of the claim language "[a] composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution," or (2) "purgation" is construed to mean "cleansing," contrary to the Federal Circuit's decision on this issue.

Whether viewed as a claim construction argument concerning "about 100 ml to about 500 ml" or "purgation," Breckenridge's argument suffers from a fundamental problem: Breckenridge argues claim construction, but it has stipulated that a limited *infringement* question is the only issue left to be decided in this case. Dkt. 41, at ¶ 3. Breckenridge's attempt to argue the scope and meaning of the claim language at this late stage is both precluded by its own stipulation and inconsistent with a motion for summary judgment of noninfringement. *See id.* [12] *See also Abraxis Bioscience, Inc. v. Mayne Pharma Inc.*, 467 F.3d 1370, 1375 (Fed. Cir. 2006) ("[a] determination of infringement requires a two-step analysis. First, the court determines the

[12] Breckenridge itself has admitted that if this Court believes claim construction is necessary to resolve Breckenridge's motion, the case must be resolved in Braintree's favor. *See* Ex. 1, at 10:18-20 (June 10, 2013 Hearing Transcript)("[I]f you rule against us on [the issue of the need to construe purgation], we have essentially given up the field of battle to Mr. Regan on the issue of purgation. So if he persuades you that purgation does need to be construed, then we will lose."); *id.* at 10:7-13 ("we are either right on the issue that you do not need to construe purgation, or we lose; that is, you find that there is infringement."); *id.* at 12 ("if you allow us to file the motion and you rule against us on purgation – that is, you find that construing that claim term is something necessary for resolution of the case – we're done").

scope and meaning of the patent claims asserted, and then the properly construed claims are compared to the allegedly infringing device.") (citation and quotation marks omitted).

Furthermore, Breckenridge's claim construction arguments are wrong on their face. Breckenridge argues that the "about 100 ml to about 500 ml limitation" is unbound by the functional limitation[13] "for inducing purgation," and instead "refers to the total amount of solution ingested by a patient to prepare the colon for surgical or diagnostic procedures." MSJ at 18-19. This position cannot be sustained for a number of reasons.

First, Breckenridge's interpretation of the volume limitation improperly reads the "for inducing purgation" limitation out of the claims of the '149 patent. Claim language must be read as a whole and individual claim limitations cannot be ignored or taken out of context. *See, e.g., Accent Packaging, Inc. v. Leggett & Platt, Inc.*, 707 F.3d 1318, 1327 (Fed. Cir. 2013); *Unique Concepts*, 939 F.2d at 1562. As the Federal Circuit agreed, when the claims of the '149 patent are read in their entirety there is no dispute that the claimed compositions of "about 100 ml to about 500 ml" are "for inducing purgation." *See* Ex. 13, at 6, 10; Ex. 6, at 6; Dkt. 86-15, at 1-22; BMF 7-9. So, the volume limitation cannot be read apart from the "purgation" limitation.[14]

Second, Breckenridge's reading of "about 100 ml to about 500 ml" would improperly render the claim language "for inducing purgation" meaningless. *See Douglas Dynamics, LLC v. Buyers Prods. Co.*, 717 F.3d 1336, 1350 (Fed. Cir. 2013) (rejecting proposed construction that would render claim terms "superfluous"); *Mangosoft, Inc. v. Oracle Corp.*, 525 F.3d 1327, 1330

[13] A functional limitation of a claim is one that describes "what [the invention] does rather than what it is." *See Halliburton Energy Svcs., Inc. v. M-I LLC*, 514 F. 3d 1244, 1255 (Fed. Cir. 2008) (citing *In re Swinehart*, 439 F. 2d 210, 212 (C.C.P.A. 1971)); *see also* 3-8 Chisum on Patents § 8.04 (2013) ("functional language" is "language describing an invention in terms of what it *accomplishes* rather than in terms of what it *is*") (emphasis in original).

[14] Any suggestion by Breckenridge that the claim language "for inducing purgation" should be ignored because it is in the preamble of the claim must be rejected as inconsistent with the Federal Circuit's decision in the Novel litigation. The Federal Circuit's statement that Braintree's "'one bottle' infringement theory … can prevail" if purgation means "something less than a full cleansing" shows that the Federal Circuit determined that the "purgation" claim term limits the remaining claim elements in the body of the claim. Ex. 13, at 6.

(Fed. Cir. 2008) (same). As the Federal Circuit recognized, purgation is the inventors' chosen methodology to achieve colon cleansing, and purgation is something less than colon cleansing. Ex. 13, at 5-8. Reading "about 100 ml to about 500 ml" to require cleansing—when the inventors chose to claim a composition that caused something less than cleansing—would improperly make the narrower functional limitation "for inducing purgation" superfluous.

Third, neither the '149 patent specification nor the file history support Breckenridge's non-infringement position. It is the claim language—not the specification or the file history—that defines the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.") (internal quotation marks omitted).

As to the specification – experimental solutions A-E described in the specification are "preferred embodiments," and the patent expressly states that those embodiments were "not intended to limit the present invention to the specific formulations shown and described." *See* Dkt. 86-4, at Col. 11:55-63. As the Federal Circuit confirmed in the *Novel Case*, it is improper to limit claim language based on embodiments described in the specification. Ex 13, at 7; *see also Falana v. Kent State Univ.*, 669 F.3d 1349, 1355 (Fed. Cir. 2012) ("[A] court may not import limitations from the written description into the claims.") (internal quotations omitted).[15]

As to the file history – Braintree's alleged "admissions" or "representations" (*see* MSJ at 12) cannot eliminate "purgation" from the claims. That very argument was rejected in the *Novel Case*. Judge Sheridan correctly determined that "these alleged admissions do nothing to

[15] Breckenridge argues that the volume of SUPREP is different from the volume of the solutions that were tested in the study described in the '149 patent specification. *See* MSJ at 8-9. As Dr. Cleveland explains in his declaration, this change was made when the commercial product was developed so that the drug would be palatable and so that the salts would remain dissolved in solution. *See* Declaration of Mark Cleveland, Ph.D. in Support of Braintree's Opposition to Breckenridge's Motion for Summary Judgment of Non-infringement ("Cleveland Decl."), at ¶¶ 5-12. This difference in volume has nothing to do with the issue of infringement.

contradict the fact that . . . one bottle of SUPREP is sufficient to cause purgation of the colon." *See* Dkt. 86-15, at 16-17. The Federal Circuit also rejected arguments based on the file history. Ex. 13, at 6-8. None of the alleged "admissions" presented by Breckenridge (many of which are irrelevant and taken out of context[16]) change the indisputable fact that the claimed compositions of the '149 patent are *for inducing purgation,* the inventors' chosen "methodology to improve visualization of the colon." *See* Ex. 6, at 6; Ex. 13 (Federal Circuit Opinion) at 7.[17]

Finally, Breckenridge's argument is contrary to how a person of ordinary skill in the art interprets the claims. The law is clear that claims must be viewed from the perspective of a person of ordinary skill in the art. *E.g., Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 n.3 (Fed. Cir. 2008). Dr. David Peura, Braintree's expert in the *Novel Case*, is a person of ordinary skill in the art of the '149 patent. *See* Peura Decl., ¶¶ 5-12. In Dr. Peura's opinion, "a person of ordinary skill in the art would understand that the purpose of the claimed 'composition' is 'for inducing purgation.'" *Id.* ¶ 61. Therefore, a person of ordinary skill in the art would read the "about 100 ml to about 500 ml" limitation together with the requirement that the composition is "for inducing purgation." Peura Decl., ¶¶ 61-63. Breckenridge's contrary interpretation should be rejected because it is entirely attorney argument—unsupported by any expert.[18] *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997) ("arguments of counsel cannot take the place of evidence lacking in the record") (internal citation omitted).

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[16] *See* Braintree's Responses to Breckenridge's Rule 56.1 Statement, at Responses to Facts Nos. 23-31.

[17] Breckenridge references Braintree's Request for Patent Term Extension in its motion. *See* MSJ at 11-12. Due to a miscommunication between Braintree and the patent attorney who worked on the patent term extension, the request was first filed on the original '149 patent claims. When the patent attorney became aware of the mistake, she filed a Supplemental Request for Patent Term Extension on the reexamined claims.

[18] Breckenridge has not offered any expert evidence on the perspective of a person of ordinary skill in the art. Breckenridge has admitted this: "I am trying … to imagine what I would put in as an expert report in this case, and I can't imagine anything that I would have an expert say." *See* Ex. 1, at 10:1-3; *see also id.* at 16:12-13 ("frankly, I can't conceive of what we would say in an expert report"). Resort to Breckenridge's counsel's arguments about the purported plain and ordinary meaning, and stipulated meaning, of the claim terms is not a substitute for how one of ordinary skill in the art would read the claims as a whole. *See Estee Lauder*, 129 F.3d at 595.

B. Breckenridge's Non-infringement Argument Relies on a Mischaracterization of its Proposed Generic Copy of SUPREP and its Proposed Indication

Breckenridge argues that its proposed product does not meet the "about 100 ml to about 500 ml" limitation of the claims of the '149 patent because it "*will be administered as* 946 ml of aqueous solution." *See, e.g.,* MSJ at 1, 19 (emphasis added). This is an inaccurate and misleading description of Breckenridge's proposed product. The undisputed evidence is that Breckenridge's proposed product will *never* be administered to a patient as 946 ml of solution; indeed, such an administration would be contrary to the proposed label Breckenridge submitted to the FDA. *See* Dkt. 86-1, at CYPRESS000007-8. Instead, like SUPREP and Novel's infringing copy, Breckenridge's proposed product will be taken in two *separate* 473 ml administrations which are separated by a 10-12 hour period. *See supra* at Section V(A); SF 34-35; BMF 56-79. Each 473 ml administration will induce purgation. SF 24-27; BMF 60, 62, 77. Each 473 ml administration likewise will infringe the asserted claims of the '149 patent.

Breckenridge also misstates the product's proposed indication when it argues that "[n]othing in the proposed labeling provides any motivation for a patient to take less than the full 946 ml dosage in order to induce diarrhea in a manner short of the sole listed indication—*colonic purgation* required in preparation for colonoscopy." MSJ at 24 (emphasis added). The indicated use for Breckenridge's proposed generic copy of SUPREP is ***not*** "colonic purgation." The FDA-approved indication for SUPREP, and the indication Breckenridge seeks for its generic copy, is "*cleansing* of the colon as a preparation for colonoscopy." SF 4, 20. As the Federal Circuit recognized in the *Novel Case*, cleansing is the ultimate goal when a patient is prescribed SUPREP— purgation, induced by each 473 ml administration, is the mechanism used to achieve that goal. *See* SF 21, 24; *see also* Ex. 13, at 6; BMF 102-103. Breckenridge's misleading statement that a patient must consume 946 ml of its generic product for "colonic purgation" is an

improper attempt to import a "cleansing" requirement into the claim.[19]

C. Breckenridge Misapprehends Infringement Under § 271(e)

In Hatch-Waxman litigation, "the substantive determination whether actual infringement or inducement will take place *is determined by traditional patent infringement analysis*, just the same as it is in other infringement suits, including those in a non-ANDA context." *Warner-Lambert*, 316 F.3d at 1365 (emphasis added); *see also Glaxo*, 110 F.3d at 1569. Breckenridge's motion suggests otherwise – that infringement under §271(e)(2)(A) is different, requiring the proposed generic product to be compared "as a whole" to the asserted claims. MSJ at 3, 20.

Breckenridge is wrong. The Federal Circuit requires a comparison of the asserted claims to the product to be sold to determine infringement; there is no case law holding that infringement of composition claims under §271(e)(2)(A) is necessarily determined by comparing the asserted claims to the *total* amount of a drug required for an approved indication. *See Glaxo*, 110 F.3d at 1569-70 (rejecting patentee's argument that §271(e)(2)(A) infringement action requires a unique infringement analysis focused solely on the ANDA); *Ferring B.V. v. Watson Laboratories, Inc.*, 764 F.3d 1401, 1408 (Fed. Cir. 2014) ("the ultimate infringement inquiry" "is focused on a comparison of the asserted patent claims against the product that is likely to be sold following ANDA approval and determined by traditional patent law principles.").

Here, Breckenridge will make, offer for sale, and sell a kit containing two bottles of

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[19] In arguing that SUPREP can *only* be considered as a 946 ml solution for purposes of patent coverage, Breckenridge also conflates the separate regimes of FDA regulatory law and patent law. FDA regulatory law is concerned with safety and efficacy. *See, e.g.,* Federal Food, Drug and Cosmetic Act of 1938, 21 U.S.C. §355 (granting the Secretary of Health and Human Services the responsibility for approval of safe and effective drugs); 21 C.F.R. Part 5 (delegating that authority to FDA). Consequently, Breckenridge's ANDA and product label direct a patient to ingest two diluted bottles of the proposed product, 10 to 12 hours apart, to achieve colon cleansing safely and efficaciously. *See* Dkt. 86-1, at CYPRESS000007. Patent infringement, by contrast, is determined by comparing the accused product against the patent claims. *Warner-Lambert*, 316 F.3d at 1365-66. Breckenridge's proposed product, by the separate administration of each of its bottles, meets the limitations of the asserted claims of the '149 patent's composition claims and directs patients to practice its asserted method claims. *See* BMF 123. Nothing more is required for infringement. *See Warner-Lambert*, 316 F.3d at 1365-66.

generic SUPREP. Each bottle in that kit, when diluted according to the product's label, infringes composition claims 15 and 18 of the '149 patent – each is a composition of "from about 100 ml to about 500 ml" that is "for inducing purgation" in a patient. *See supra* at Section V(A); BMF 22, 39, 47-52, 59-65, 73-77, 80-83. The total volume of SUPREP required for the FDA-approved indication of cleansing is not relevant to Breckenridge's infringement of those claims.[20] A composition infringes a patent claim, not an FDA-approved label.

D. Braintree's Infringement Argument Does Not Improperly Divide the Accused Product

Breckenridge argues that Braintree improperly divides the accused product by "artificially 'carv[ing] out a portion' of the accused product in an attempt to show infringement of a claimed range." *See* MSJ at 2, 20-21. This argument misapplies the law. The "carve out" language in *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377 (Fed. Cir. 2000), relied upon by Breckenridge, stands for the unremarkable proposition that a patentee may not import a functional limitation into asserted claims "[w]here the function is not recited in the claim itself by the patentee." *Ecolab, Inc. v. Envirochem, Inc.*, 264 F.3d 1358, 1367 (Fed. Cir. 2001).[21]

The District Court for the District of Delaware has further explained that the purpose of the "carve out" language in *Jeneric/Pentron* is to prohibit an "attempt to artificially decompose a single … component into sham sub-components." *Dow Chem. Co. v. NOVA Chem. Corp.*, 629

[20] Breckenridge argues that its proposed product does not infringe under §271(e) because its proposed label defines the product as a two-bottle kit. *See* MSJ 6-7, 19. Breckenridge misstates the law. As under §271(a), the focus of the infringement analysis under §271(e) remains on the product that will be sold. Allowing a generic manufacturer to define its proposed product in an ANDA filing to avoid infringement under §271(e) could create a bizarre scenario where there could be no infringement under §271(e), but the same product could be found to infringe under §271(a) after it is actually made, used or sold in the United States. Such a scenario would frustrate Congress' intent of providing an expedited infringement remedy for NDA holders prior to a generic product entering the market. *See, e.g., Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676-77 (1990) (describing the streamlined ANDA approval process and the "important new mechanism" of §271(e)(2) infringement "designed to guard against infringement of patents relating to pioneer drugs").

[21] A court in this district has similarly interpreted the "carve out a portion" language in *Jeneric/Pentron* to proscribe importing functional limitations into patent claims. *See Novartis Pharms. Corp. v. Apotex Corp.*, No. 02CIV.8917 (KMW)(HBP), 2006 WL 626058 at *8 (S.D.N.Y. Mar. 13, 2006) (Pitman, U.S.M.J.).

F. Supp. 2d 397, 408 (D. Del. 2009) (Farnan, D.J.) (finding *Jeneric/Pentron* inapplicable because the division of the accused product into "unique polymer components" was not a sham because the patent claims referenced the "possibility of multiple unique polymer components").

Jeneric/Pentron's "carve out" holding is inapplicable here. Braintree's infringement argument does not import a non-existent functional limitation into the asserted claims of the '149 patent, nor does it decompose a single component into ***sham sub-components***. *See Ecolab*, 264 F.3d at 1367; *Dow Chem.*, 629 F. Supp. 2d at 408. Rather, Braintree's infringement position relies, as it ***must*** under the law, on an ***express claim term***: "for inducing purgation." Separately evaluating, as the Federal Circuit did for Novel's product, each individual bottle of Breckenridge's proposed generic SUPREP does not constitute "artificially decompos[ing] a single . . . component into sham sub-components." *See Dow Chem.*, 629 F. Supp. 2d at 408.[22]

Breckenridge tries to make *Jeneric/Pentron* applicable by contending that "Braintree attempts to argue that only a portion of Breckenridge's ANDA Product acts to 'induce purgation,' while the additional volume ingested by the patient performs some other undefined function." MSJ at 21. But Braintree has never argued that the additional volume performs "some other undefined function." Just as in the *Novel Case*, Braintree's position is that the second 473 ml diluted bottle of solution—taken 10 to 12 hours after the first bottle, per Breckenridge's proposed label—induces purgation, as Breckenridge has stipulated. *See* SF 24-26, 41; BMF 77. Thus, *each* bottle that Breckenridge intends to make and sell, when prepared according to the product's proposed label, will infringe the composition claims of the '149

[22] For these reasons, Breckenridge's example of a 15mg pill being split in half is inapplicable.

patent, not just the first bottle. [23], [24]

E. Breckenridge's Assertion that Purgation is an "Off-Label" Use Lacks Merit

Breckenridge cites *Warner-Lambert* and its progeny to argue that its proposed generic copy of SUPREP does not meet the volume limitation of the '149 patent claims because the only approved, "on-label" use for its proposed product is colon cleansing—not purgation. MSJ at 14--15, 19-21. Breckenridge's argument fails because "purgation" and colon "cleansing" are not two distinct uses for SUPREP, one of which is off-label. Instead, purgation is the *mechanism* to achieve the *goal* of colon cleansing (the FDA-approved indication). *See* Ex. 13 (Federal Circuit Opinion), at 7; Dkt. 86-15, at 14-16; Ex. 6, at 6. Without purgation, colon cleansing is not possible. SF 8 ("SUPREP cleanses the colon of a patient by inducing copious, watery diarrhea").

It is indisputable that two bottles of SUPREP (and Breckenridge's generic copy) cannot be administered without administration of each individual bottle. Administration of one bottle cannot logically be an off-label use where the FDA-approved label itself requires that SUPREP be administered in a split-dose regimen—one bottle at a time, 10-12 hours apart. SF 34-36, 41. Breckenridge's proposed label instructs its patients to take one 473 ml bottle of diluted solution the evening before the colonoscopy, and a second 473 ml bottle of diluted solution the day of the

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[23] *Jeneric/Pentron* – which did not address infringement by an ANDA applicant – is further distinguishable on its facts. The claims there were directed to a porcelain dental composition containing 0-1% of cerium oxide. Although the accused product contained 1.61% cerium oxide, outside the claimed range, the patentee maintained that it infringed because a 0.69% portion of its cerium oxide served a different function from that discussed in the patent specification. Because the patentee's only infringement argument was that a portion of cerium oxide *contained in any sample of the accused product* should be disregarded, the court rejected this as an "attempt to carve out a portion" of the accused product. *See Jeneric/Pentron*, 205 F.3d at 1382-83. By contrast, nothing in Breckenridge's individual 473 ml bottle of diluted solution is disregarded: each bottle in Breckenridge's proposed kit meets every limitation of and infringes the asserted composition claims.

[24] It is Breckenridge, not Braintree, that runs afoul of clear Federal Circuit precedent by urging this Court to do the—equally prohibited—inverse of the prohibited conduct in *Jeneric/Pentron*. As explained above in Section VI(A), Breckenridge argues that this Court should read the functional claim limitation "for inducing purgation" out of the asserted claims. *See Accent Packaging*, 707 F.3d at 1327*; Unique Concepts*, 939 F.2d at 1562; *Perkin-Elmer Corp. v. Westinghouse Elec. Corp*., 822 F.2d 1528, 1532-33 (Fed.Cir.1987) (holding that all the limitations of a claim must be considered meaningful).

colonoscopy. *See* Dkt. 86-1, at CYPRESS000007-8; SF 34. Each 473 ml bottle of diluted solution induces purgation. SF 24-26, 41. The purgation mechanism is also set out in the Braintree and Breckenridge labels, which state that "[t]he osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhea." Ex. 10, at BRTSUP00000136; Dkt. 86-1 at CYPRESS000018; *see also* Ex. 13 at 5, 7-8; Dkt. 86-15, at 16. Use of one bottle for inducing purgation is decidedly "on label."

Breckenridge's argument suggests nonsensically that its label instructs patients to consume its product *off*-label twice to use the product "on-label" for its approved indication. The reality is simpler: the administration of Breckenridge's product as described in its proposed label—administration of two bottles, each diluted to 473 ml, 10 to 12 hours apart—leads to two distinct instances of infringement of method claims 19 and 20 of the '149 patent.

Furthermore, Breckenridge's "off label use" argument improperly conflates the infringement analysis for method and composition claims. It is indisputable that if approved by FDA, Breckenridge will make and sell a kit that contains two bottles, each of which will be a composition of "about 100 ml to about 500 ml" for inducing purgation when prepared according to the proposed label. Accordingly, each of the two bottles will infringe composition claims 15 and 18 of the '149 patent. For these reasons, Breckenridge's motion for summary judgment should be denied. Dkt. No. 41 ¶3; *see* Peura Decl., ¶ 78.

1. The Cases Breckenridge Cites Are Inapposite

The law Breckenridge cites to support its "off-label" argument is inapplicable here. First, most of these cases relate to method-of-treatment claims, where the claims at issue covered specific ***uses*** of a drug to treat disease, not the drug ***composition*** itself. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012); *AstraZeneca 2010*, 633 F.3d at 1048, 1057; *Allergan v. Alcon Labs.*, 324 F.3d 1322, 1323 (Fed. Cir. 2003); *Warner-Lambert*,

316 F.3d at 1352. As Judge Sheridan determined in the *Novel Case*, these holdings provide "no guidance" with respect to drug ***composition*** claims, such as claims 15 and 18 in this case. *See* Dkt. 86-15, at 16; *see also AstraZeneca Pharms. LP v. Apotex Corp.*, 669 F.3d 1370, 1379 (Fed. Cir. 2012) ("[A]n ANDA seeking to market a drug *not covered by a composition patent for unpatented methods of treatment* cannot infringe under § 271(e)(2)."") (emphasis added).

But even as to Braintree's asserted method claims, the cases are inapposite. *Bayer-Schering*, *Allergan*, and *Warner-Lambert* all stand for the proposition that "a method of use patent holder may not sue an ANDA applicant for induced infringement of its patent, if the ANDA applicant is not seeking FDA approval ***for the use*** claimed in the patent and if the use claimed in the patent is not FDA-approved." *Allergan*, 324 F.3d at 1332-33 (citing *Warner-Lambert*, 316 F.3d at 1354-55) (emphasis added); *see also Bayer-Schering*, 676 F.3d at 1320-21. In other words, these cases hold that an ANDA applicant cannot induce infringement of claims if its proposed label does not require patients and doctors to practice a claimed method.

In each of these three cases, the NDA holder asserted infringement of a patent for a ***use that was not FDA-approved***, while the ANDA holder sought approval to market the drug for an entirely different FDA-approved use.[25] In each case, it would have been *illegal* for the ANDA applicant to market a product for the purpose claimed in the patent-in-suit, because the applicant did not seek FDA permission to make and sell such a product.[26] Naturally, infringement—which

[25] *See Bayer-Schering*, 676 F.3d at 1326 (finding no infringement where patent covered use of drug simultaneously for non-FDA-approved antiandrogenic and anti-mineralocorticoid effect, and approved contraceptive effect, while ANDA filer sought approval only for contraceptive effect); *Allergan*, 324 F.3d at 1327-28, 1334 (finding no infringement where patent covered non-FDA approved use of drug for protection of optic nerve and neural protection, while ANDA filer sought approval for FDA-approved use of drug to reduce intraocular pressure); *Warner-Lambert*, 316 F.3d at 1351-52, 1366 (finding no infringement where patent covered non-FDA-approved use of drug for treatment of neurodegenerative disease, while ANDA filer sought approval for FDA-approved use of drug for treatment of epilepsy).

[26] *See, e.g., Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1249-50 (Fed. Cir. 2000) (cataloging the severe civil and criminal sanctions for marketing a drug not approved by the FDA, or for failing to adhere to the specifications disclosed in the ANDA).

focuses on the product the ANDA applicant will likely market—was not found. As the Federal Circuit succinctly stated in *Warner-Lambert*:

> Here, the request to make and sell a drug labeled with a permissible (non-infringing) use cannot reasonably be interpreted as an act of infringement (induced or otherwise) with respect to a patent on an unapproved use, ***as the ANDA does not induce anyone to perform the unapproved acts required to infringe.***

Warner-Lambert, 316 F.3d at 1364-65 (emphasis added).[27]

There are no such facts here. Patients and doctors following the instructions in Breckenridge's proposed label *must* infringe method claims 19, 20, and 23 of the '149 patent. *See supra* at Section V(A). Cleansing is the FDA-approved indication for SUPREP, as well as the indication sought by Breckenridge for its proposed generic copy. *See* SF 4, 20. Purgation is the mechanism to achieve cleansing. *See* Ex. 13 (Federal Circuit Opinion), at 7; Ex. 6, at 6; Dkt. 86-15, at 33-34; SF 8, 21, 25. To use Breckenridge's generic product for cleansing, that product must first induce a purgation. SF 21, 24-26, 41. In other words, when a patient uses Breckenridge's copy of SUPREP for the approved indication of colon cleansing, it necessarily will infringe the method claims of the '149 patent.

Breckenridge cites a single case, *Bayer AG*, 212 F.3d 1241, for the proposition that the principles of *Warner-Lambert* apply to composition claims. MSJ at 16. Breckenridge's counsel argued that *Bayer AG* stands for the proposition that "[a]ll we have to look at in an ANDA case is the ANDA itself. It will tell us all we need to know because the ANDA defines the product." *See* Ex. 1, at 12:1-3. Once again, Breckenridge misreads the law. In *Bayer AG*, the generic defendant would never practice the claims of the patent-in-suit because the ANDA and the patent claims recited mutually exclusive, non-overlapping compositions. *Bayer AG*, 212 F.3d at 1249-

[27] *See also Takeda Pharm. U.S.A., Inc. v. West-Ward Pharm. Corp.*, 785 F.3d 625, 627, 630-32, 633-34 (Fed. Cir. 2015) (finding no likelihood of infringement because generic's label for "*prophylaxis*" of gout flares that stated, "tell your healthcare provider" if a gout flare occurs, did not actively encourage nor "necessarily lead" to "*treatment*" of gout flares as recited in the asserted method claims).

50. The patent-in-suit claimed a solid composition containing crystals with a "specific surface area" ("SSA") within the range of 1.0 to 4 m^2/g. *Bayer AG*, 212 F.3d at 1246. The defendant's ANDA specified that its proposed product would have an SSA of 5 m^2/g or greater. *Id.* at 1246, 1249. Given that the ANDA controls the composition of the product, the Federal Circuit, focusing on the "product that will be sold," held that the proposed generic product did not infringe because, if approved by FDA, it would not (and could not) have the claimed SSA. *See id.* at 1249-50. Unlike in *Bayer AG*, Breckenridge's generic copy of SUPREP, prepared according to its ANDA, will meet every limitation of the asserted composition claims of the '149 patent, including the "about 100 ml to about 500 ml" limitation. Each 473 ml bottle of diluted solution, prepared according to Breckenridge's ANDA, is a composition of "about 100 ml to about 500 ml" "for inducing purgation." *See supra* at Section VI(A).

VII. CONCLUSION

For the reasons stated above, Braintree respectfully requests that this Court deny Breckenridge's Motion for Summary Judgment of Non-infringement. Breckenridge has stipulated that "If the Court denies [Breckenridge's] Motion, [Breckenridge] stipulates that its proposed generic version of Braintree's SUPREP… infringes claims 15, 18, 19, 20, and 23 of the '149 Patent." Dkt. 41, at ¶ 3; *see also* Ex. 1, at 10:7-13 (June 10, 2013 Hearing Tr.). Therefore, Braintree also respectfully requests that this Court enter judgment against Breckenridge and for Braintree that Breckenridge and its proposed generic copy of SUPREP infringe asserted claims 15, 18, 19, 20, and 23 of the '149 patent.

Dated: July 20, 2015

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CERTIFICATE OF SERVICE

I hereby certify that on July 20, 2015, a true and correct copy of the foregoing BRAINTREE LABORATORIES INC.'S OPPOSITION TO DEFENDANT BRECKENRIDGE PHARMACEUTICAL, INC.'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT was filed through the Court's Electronic Filing System (ECF), and was served electronically to the registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: July 20, 2015 /s/ John J. Regan